

## Message Text

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11

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-05

EB-07 COME-00 /066 R

66616

DRAFTED BY DHEW/FDA/JRWEINROTH

APPROVED BY OES/APT/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EA/ANP:MMICHAUD (INFO)

EA/J:DBROWN (INFO)

EUR/NSC-IG:JROUSE (INFO)

AF/S:RDOLS (INFO)

NEA/IRN:BMORTON (INFO)

NEA/IAI:WSMITH (INFO)

ARA/MEX:GFALK (INFO)

----- 003040

R 282132Z AUG 75

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY HELSINKI

AMEMBASSY PARIS

AMEMBASSY TEHRAN

AMEMBASSY TEL AVIV

AMEMBASSY ROME

AMEMBASSY TOKYO

AMEMBASSY MEXICO

AMEMBASSY THE HAGUE

AMEMBASSY PRETORIA

AMEMBASSY MADRID

AMEMBASSY STOCKHOLM

AMEMBASSY BERN

AMEMBASSY LONDON

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E.O. 11652: N/A

TAGS: ETRD, OGEN, TBIO, AS, FI, FR, IR, IS, IT, JA, MX,

NL, SF, SP, SW, SZ, UK.

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SUBJECT: FDA ADVISORY - DEFECTIVE HEART VALVES

1. FDA ADVISES THAT HEART VALVES (AORTIC AND MITRAL) MANUFACTURED  
BY SHILEY LABORATORIES, INC. 17600 GILLETTE AVENUE SANTA ANA,

CALIF. 92705, "FABRICATION ORDER NUMBERS" 07612, 09211, 01-791 ARE DEFECTIVE IN THAT THE DEVICES HAVE FAILED DUE TO SEPARATION OF THE LOWER STRUT FROM THE MAIN VALVE BODY OF OF IMPLANTED VALVES. THREE SUCH FAILURES HAVE OCCURRED RESULTING IN TWO KNOWN DEATHS.

2. EACH VALVE IS INDIVIDUALLY SEALED IN A SMALL PLASTIC BAG WHICH IN TURN IS CONTAINED IN A PLASTIC BOX. ALSO CONTAINED IN THE PLASTIC BOX IS AN INSTRUCTIONAL BROCHURE ENTITLED: "SHILEY-?94(-SHILEY CARDIAC VALVE PROSTHESIS CARE AND HANDLING INSTRUCTIONS" AND AN IMPLANTATION DATA CARD. THE OUTER LABELING ON THE PLASTIC BOX DESCRIBES THE DEVICE, ITS SIZE, TYPE OF VALVE DISC, AND ITS SERIAL NUMBER. IN ADDITION, THE LABEL STATES THAT THE VALVE IS NON-STERILE AND WAS MANUFACTURED BY SHILEY LABORATORIES, INC. THE FIRM USES FABRICATION ORDER NUMBERS TO INTERNALLY IDENTIFY "BATCHES" OF VALVES. EACH VALVE ITSELF IS IDENTIFIED WITH A 3 OR 4 DIGIT SERIAL NUMBER WHICH FOLLOWS A SEQUENCE OF NUMBERS AND LETTERS FOR IDENTIFYING THE VALVE SIZE AND TYPE (E.G. 29MBRP5071 - THE 29 REPRESENTS THE SIZE OF THE VALVE OPENING IN MILLIMETERS, MBRP REPRESENTS MITRAL SUPRA ANNULAR SEWING RING, PYROLITIC CARBON DISC, AND 5071 REPRESENTS THE 4 DIGIT SERIAL NO.). NOTE - THE FIRM IS RECALLING BY INDIVIDUAL SERIAL NUMBERS OF NON-IMPLANTED VALVES.

3. FOREIGN CONSIGNEES AS FOLLOWS:

A. E. STANSEN AND CO. PTY. LTD.                      31MBP956  
P.O. BOX 118 MOUNT WAVERLEY  
VICTORIA 3149 AUSTRALIA

INSTRUMENTARIOU                      29MBRP4740  
HOSPITAL & LABORATORY DIVISION                      29MBP1707  
ELIMAENKATU 22                      31MBRP4026 29MBP112  
0  
HELSINKI, 51, FINLAND

TRANSPORTS CLASQUIN                      29MBRP5090 31ABP794  
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AIRPORT AT LYON/BRON                      29MBRP5095  
FOR ACCOUNT OF CLIMO S.A.                      29MBRP5097  
39, BD AMBROISE PARA                      29MBRP5107  
69008 LYON, FRANCE                      29MBRP5112  
29MBRP5113  
29MBRP5114  
29ABP2258  
29ABP2259  
31MBRP4098

PAHLAVI UNIVERSITY (IRAN BEHDASHT TEHERAN,  
IRAN)                      29ABP1091  
DEPARTMENT OF SURGERY                      29MBRP1469

(OPEN HEART SURGERY)

SHIRAZ, IRAN

QUEEN PAHLAVI FOUNDATION 29MBRP4755

TEHERAN 29MBRP4765

31MBRP4078

ORDER OF: BANK OMRAN

ISTANBUL AVE.

TEHERAN, IRAN

IRAN BEHDASHT CO. LTD. 29MBP1876

118-122 TAKHTE JEMSHID AVE. WEST

TEHRAN, IRAN

UNIVERSITY OF TEHERAN 31MBRP1494

FACULTY OF MEDICINE

TEHERAN UNIVERSITY

TEHERAN, IRAN

MEDTECHNICA LTD. 29MBP1718

P.O.B. 2695

18A KING GEORGE ST. (ALMONIT LN)

TEL-AVIV ISRAEL

GOVERNMENT OF ISRAEL SUPPLY MISSION 31MBRP4667

C/O RANDY INTERNATIONAL LTD.

147-95 FARMERS BLVD.

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JAMAICA NEW YORK 11343

##SINCE THIS UNIT WAS SHIPPED TO A

DOMESTIC ADDRESS, IT IS ALSO

LISTED ON THE DOMESTIC LIST.

P. BARENZO 29MBRP4367 31AB236

FORLANINI AIRPORT 29MBRP4369 29MBR103

9

MILANO, ITALY 29MBRP4712

29MBRP4713

29MBUP510

31MBRP4040

31MBRP4041

31MBRP4046

BOSA 31MBR628

VIA REVERE 16 31MBR631

MILANO, ITALY

SENKO MEDICAL TRADING CO. 29MBRP5166

23-13 3-CHOME HONGO

BUNKYO-KU 29ABP2428

TOKYO, JAPAN 29MBP1703  
29MBP1863  
31MBP1634  
31MBP1652  
31MBP1718 29MBP1286

SOLD TO SENKO MEDICAL 29MBP1999  
TRADING CO.

23-13 3-CHOME HONGO 29MBP2000  
BUNKYO-KU 29MBP2005

TOKYO JAPAN

SHIPPED TO:

MR. HIDEO UNO

11270 #-6534 -;3.

CULVER CITY, CALIFORNIA 90230

##SINCE THESE UNITS WERE SHIPPED TO A  
DOMESTIC CONSIGNEE, IT IS ALSO  
LISTED ON THE DOMESTIC LIST.

PROVEDORA CLINICA 29MB1727  
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PUEBLA NO. 109 29MB1728  
3 178,- :94\$9?- 31MB1280  
MEXICO 7 D.F. 31MB1281  
31MB1287

N. V. HANDELSMAATSCHAPPIJ HILEKES 29MBRP4673  
STARGARDLAAN 13 29MBRP4675  
POSTBUS 202 P.O. BOX 202 29MBRP4676  
BUSSUM HOLLAND 29MBRP4679  
29MBRP4680  
29MBRP4778  
29MBRP4839

N.V. HANDELSMAATSCHAPPIJ HILEKES 29ABP2294  
31MBP979 29ABP2309 31MBP1693  
31MBRP1482 29ABP2310 31MBP1738  
31MBRP1905 29ABP2356 31MBRP402

2

29MBP1251 (IMPLANTED)

FREDRICK C. MARCUS & CO. LTD. 29MBRP4684  
7TH FLOOR MONTE CARLO 29MBRP4685 (IMPLANTE  
D)  
HEERENGRACHT FORESHORE 29MBRP4686  
CAPE TOWN, SOUTH AFRICA 31MBRP4031  
31MBRP4032  
31MBRP4062

PRODUCTOS MEDICO-QUIRURGICOS S.A. 29MBRP4348 (IMPLANTE  
D)  
C/O BAKUMAR S.A. 29MBRP4693  
RAMBLAS 30 29MBRP4698

BARCELONA 6 SPAIN 29MBRP4723  
29MBRP5075  
29MBRP5194  
29MBP1869  
29MBP1871  
29MBP1872  
29MBP1659

WILSON COMPANY A.B. 31MBUP514  
FACK 10250  
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STOCKHOLM 27 SWEDEN

HILKES MEDICAL A.G. 29MBRP4355 (IMPLANTE  
D)  
STEINHAUSERSTRASSE 23 31MBRP4057  
6301 ZUG 31MBRP4348  
SWITZERLAND

HAUSMANN INC. 29MBP2105  
MARKTGASSE 11  
CH9001 ST. GALL  
SWITZERLAND

CHAS. F. THACKRAY LTD. 29MBRP4644  
C/O MORRISON AIR GROUP 29MBRP4818  
LEEDS/BRADFORD AIRPORT 29MBRP4821  
YEADON NR. LEEDS ENGLAND 29MBRP5133  
29MBRP5151  
33XMBRP105

31MBRP1315 31MBRP3396 (IMPLANTE  
D)  
31MBRP2034 31MBRP4001  
31MBR636 31MBRP4002  
31MBR639 31MBRP4011  
31MBR634 31MBRP4014  
31MBR647 31MBRP4018  
31MBR646 (IMPLANTED) 31MBRP4020 (IMPLANTE  
D)  
29AB669 31MBRP4367  
29MBR927 31MBRP4369  
31MBRP4355

4. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO  
DETERMINE IF THEY ARE FAMILIAR WITH DETAILS OF ADVISORY  
AND MAY ALSO WISH TO NOTIFY HOST GOVERNMENT CONTROL AUTHORITIES  
EXERCISING JURISDICTION OVER SUCH DEVICES. ANY QUESTIONS  
REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM.  
INGESOLL

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<< END OF DOCUMENT >>

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 26 AUG 1999  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** FOOD & DRUG REGULATIONS, MEDICAL EQUIPMENT, RECALL  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 28 AUG 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1975STATE205330  
**Document Source:** ADS  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/JRWEINROTH  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** n/a  
**Film Number:** D750299-0864  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1975/newtext/t19750898/baaaaai.tel  
**Line Count:** 271  
**Locator:** TEXT ON-LINE, TEXT ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 5  
**Previous Channel Indicators:**  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** hartledg  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 02 JAN 2003  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <02 JAN 2003 by ReddocGW>; APPROVED <23 JAN 2004 by hartledg>  
**Review Markings:**

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US Department of State  
EO Systematic Review  
06 JUL 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** <DBA CORRECTED> gwr 971008  
**Subject:** n/a  
**TAGS:** ETRD, OGEN, TBIO, AS, FI, FR, IR, IS, IT, JA, MX, OGEN  
**To:** CANBERRA  
HELSINKI  
PARIS  
TEHRAN  
TEL AVIV  
ROME

TOKYO  
MEXICO  
THE HAGUE  
PRETORIA  
MADRID  
STOCKHOLM  
BERN  
LONDON

**Type:** TE

**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006